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Donald J. Bird
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In Re: Patent Term Extension
Application for
U.S. Patent No. 5,434,171

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 5,434,171, which claims the human drug product ENTEREG® (alvimopan), formulations of ENTEREG® (alvimopan) and methods of using ENTEREG® (alvimopan), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 5,250,542 based on the regulatory review period for the ENTEREG® (alvimopan), NDA No. 21-775.

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified patent will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted. (A certificate of extension will be issued to U.S. Patent No. 5.250,542.) In the absence of such request for reconsideration and if U.S. Patent No. 5,434,171 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 5 years in U.S. Patent No. 5,434,171.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of October 9, 2009 (74 Fed. Reg. 52241), would be 3,059 days. Under 35 U.S.C. § 156(c):

$$\text{Period of Extension} = \text{RRP} - \text{PGRRP} - \text{DD} - \tfrac{1}{2}(\text{TP} - \text{PGTP})^{1}$$

[1] Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act

= 5,305 - 614 - 0 - ½ (3,879 - 614)
= 3,059 days (8.4 years)

Since the regulatory review period began November 12, 1993, before the patent issued (July 18, 1995), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From November 12, 1993, to and including July 18, 1995, is 614 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation, because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(A), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,434,171
Granted:	July 18, 1995
Original Expiration Date[2]:	December 8,2013
Applicant:	Scott A. Frank et al.
Owner of Record:	Eli Lilly and Company
Title:	Preparation of 3,4,4-Trisubstituted Piperidinyl-N-Alkylcarboxylates and Intermediates
Product Trade Name:	ENTEREG® (alvimopan)

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with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of ½ (TP - PGTP).

[2]Subject to the provisions of 35 U.S.C. § 41(b).

Term Extended: 5 years

Expiration Date of Extension: December 8, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: ENTEREG® (alvimopan)
Docket No.: FDA-2009-E-0015